
Scotopic measurement of normal pupils: Colvard versus Video Vision Analyzer infrared pupillometer

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ABSTRACT

Purpose: To prospectively measure the scotopic pupil diameter in a normal population and to compare 2 infrared pupillometers for these measurements.

Setting: Johann Wolfgang Goethe-University, Department of Ophthalmology, Frankfurt am Main, Germany.

Methods: The Colvard infrared pupillometer was compared to the Video Vision Analyzer (VIVA) infrared pupillometer under scotopic light conditions in 33 participants (aged 19 to 55 years). Reliability was assessed by 2 independent examiners (E1, E2). Statistical analysis was performed using a comparison method by Bland and Altman.

Results: Mean pupil diameter was $6.16 \text{ mm} \pm 1.20 \text{ (SD)}$ (range 3.20 to 9.00 mm) with all measurements taken under scotopic illumination. The mean scotopic pupil diameter was $6.08 \pm 1.16 \text{ mm}$ (range 3.2 to 8.4 mm) with the Colvard pupillometer and $6.24 \pm 1.28 \text{ mm}$ (3.5 to 9.0 mm) with the VIVA pupillometer. The mean differences between the Colvard and VIVA were -0.27 mm (E1) and -0.05 mm (E2). Limits of agreement ranged from 1.4 (Colvard) to 2.4 (VIVA). The coefficients of repeatability ranged from 0.7 (Colvard) to 1.1 (VIVA).

Conclusions: A mean scotopic pupil diameter of 6.15 mm with a maximal pupil size of 9.00 mm can be expected in a normal population; this should be considered in refractive corneal and refractive lens surgery. Measurements with the Colvard pupillometer were more reliable and precise than those with the VIVA pupillometer. *J Cataract Refract Surg* 2000; 26:859–866 © 2000 ASCRS and ESCRS

Pupil diameter is a limiting factor to a perfect outcome after corneal and refractive lens surgery. Halos, star bursts, and glare may develop after laser ablation with a small optical zone or implantation of

phakic intraocular lenses (IOLs) in patients with large scotopic pupils. Optical glare phenomena at the optical transition zone of the cornea or at the IOL optic edge are considered responsible for these effects.^{1–6} Preoperative measurement of pupil size, especially under scotopic light conditions, is therefore becoming increasingly important.⁷

An infrared device seems more reliable than the Rosenbaum card as a method of comparing pupil diameters. With the Rosenbaum card, the examiner matches

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the horizontal pupil diameter with a series of increasing half-circle diameters, which can have a tendency to underestimate pupil size.⁸

An infrared pupillometer (Colvard pupillometer) was developed for refractive surgery.⁷ We compared this device to a video-driven infrared pupillometer, the Video Vision Analyzer (VIVA), under dim light conditions to evaluate scotopic pupil diameter in a normal population.

Patients and Methods

Participants

Scotopic pupil diameter in 66 eyes of 33 participants (20 women, 13 men) with a mean age of 36 years $\pm$ 9 (SD) (range 19 to 55 years), which represents a normal population likely to have refractive surgery, was measured after 2 minutes of dark adaptation. No participant had difficulty fixating. Participants were excluded if they had a history of eye disease, eye surgery, eye trauma, topical eyedrop use, systemic drug or alcohol abuse, or slitlamp evidence of pupil or iris abnormalities. Mean sphere determined by objective refractometry (model RM-A 2300, Topcon) was -0.45 ± 1.95 diopters (D) (range $+3.50$ to -5.50 D), and mean cylinder was -0.64 ± 0.59 D (range -0.25 to -2.75 D).

Before measurement, participants answered a questionnaire in which they subjectively rated their glare sensitivity and night vision. Scores ranged from 0 to 3 (glare sensitivity: 0 = none, 1 = mild, 2 = moderate, 3 = severe; night vision: 0 = very good, 1 = good, 2 = reduced, 3 = very reduced).

Measurements Under Scotopic Illumination

Examinations were performed with 2 devices: the Colvard pupillometer (Oasis Medical) (Figure 1, A) and the Video Vision Analyzer (VIVA) pupillometer (Fortune Optical) (Figure 2, A). The measurements were taken and randomized independently by 2 examiners (E1, E2). As described by Salz,⁶ the level of light typically encountered while driving on a suburban street at night can be reproduced by turning off all the lights in a windowless examination room and cracking the door slightly to hallway light. The manufacturer of the Colvard pupillometer recommends opening the door 1 to 2 inches. The level of luminance produced with this



A



B

Figure 1. (Schnitzler) A: The Colvard pupillometer. B: The device is held 2 to 3 inches from the eye, and a millimeter ruler is superimposed by a reticule in the device, which allows direct measurement. The photograph is taken with room light, although the measurements in this study were taken under low-light conditions.

method typically ranges between 0.5 to 0.6 luxes. Under this lighting condition, scotopic pupil diameter can be easily measured with both pupillometers.

The handheld Colvard pupillometer (Figure 1, A) uses light amplification technology. A photo cathode is stimulated by low-level light energy. Electron excitation, by which a phosphor screen is stroked and the image intensified, is provoked. The device is held 2 to 3 inches from the participant's eye (Figure 1, B). A protective bar that can be attached to the forehead protects the eye and controls distance. Then, the light amplification button is pressed and a bright enhanced image can be seen. The examiner is able to focus the iris and pupil by moving the pupillometer slightly forward and back. The participant is asked to fixate on a red light. A millimeter ruler is

**A****B**

Figure 2. (Schnitzler) *A*: The VIVA pupillometer. *B*: Three images of the pupil size are taken by infrared light. The photograph is taken with room light, although the measurements in this study were taken under low-light conditions.

superimposed by a reticule in the device, which easily allows direct measurement.

The electronic VIVA pupillometer (Figure 2, *A*) allows binocular measurement of the dark adapted pupil. The participant sits 1 meter in front of and beneath the device and fixates on a red light (Figure 2, *B*). Both eyes are focused on a rectangular field on the pupillometer display. Then, a button is pressed and the device automatically takes 3 images by infrared light. By digital processing, the pupil diameter under scotopic light conditions is calculated. Precise measurements within 0.3 mm at 1 meter are possible.

Statistical Analysis

Statistical analysis was performed with the method described by Bland and Altman^{9,10} using the BIAS

Table 1. Mean scotopic pupil measurements.

Device	Mean $\pm$ SD (mm)
Colvard	
E1	6.08 $\pm$ 1.18
E2	6.08 $\pm$ 1.13
Overall	6.08 $\pm$ 1.16
VIVA	
E1	6.35 $\pm$ 1.34
E2	6.12 $\pm$ 1.21
Overall	6.24 $\pm$ 1.28

E1 = examiner 1; E2 = examiner 2

software designed by Ackermann.¹¹ This method compares 2 entities by plotting their means against their differences. The more common regression analysis was considered; however, it provides a regression coefficient of 1.0, implying perfect correlation when, for example, 1 technique measures twice as much as another technique. This is misleading when ascertaining only whether 2 techniques are interchangeable. Using Bland and Altman's method, the best correlation between 2 techniques would be if means and differences were of the same values. If the mean differences within the mean $\pm$ 2 standard deviations (SDs) would not be clinically important, the 2 measurement methods can be used interchangeably. Furthermore, the method calculates the limits of agreement between 2 methods and the interrater reliability of 2 examiners.

The limits of agreement were defined as the mean differences in measurements using the 2 techniques $\pm$ 2 standard deviations. For each pupillometry technique, the coefficients of interrater repeatability were defined as twice the standard deviation of the differences between both examiners' measurements. Lower values indicate higher repeatability.

The Student *t* test for unpaired groups was performed to prove statistical significance of scotopic pupil diameter measurements by iris color. A *P* value of 0.05 or less was considered significant. Correlation coefficients of scotopic pupil diameters and age were calculated using Microsoft Excel 97. The correlation graph was created with GraphPad Prism 2.01.

Results

Pupil Diameter

The mean scotopic pupil diameter was 6.08 ± 1.16 mm with the Colvard pupillometer and 6.24 ± 1.28 mm with the VIVA pupillometer (Table 1). Both examiners (E1, E2) calculated similar values for the 2 devices; however, the values varied more with the VIVA pupillometer.

The comparison of the 2 devices by each examiner showed a good correlation; less bias was found in the results of E1 (Figure 3, *A, B*). The scotopic pupil size measurements of both examiners using the Colvard pupillometer correlated better than the measurements with the VIVA pupillometer (Figure 3, *C, D*).

Examiner Agreement

The mean differences between pupillometers were small for both examiners (Table 2; Figure 4, *A* and *B*).

However, there was a smaller mean difference measurement by E2 (-0.05) than E1 (-0.27). The mean differences between examiners were also small for both pupillometers (Table 3; Figure 4, *C, D*). A comparison of both examiners revealed a smaller mean difference for the Colvard (0.01 mm) than for the VIVA (0.23 mm) pupillometer. The range of error within the limits of agreement (2 SD) was smallest in measurements with the Colvard pupillometer and largest in the measurements by E1 (Figure 4, *A* to *D*). In Figure 4, most of the scatter points were within the area of mean ± 2 SD.

Repeatability

The coefficient of interrater repeatability was smaller for the Colvard (0.7) than for the VIVA (1.1) pupillometer. The range of mean differences between the examiners was smaller with the Colvard than with the VIVA pupillometer (Figure 4, *C, D*).

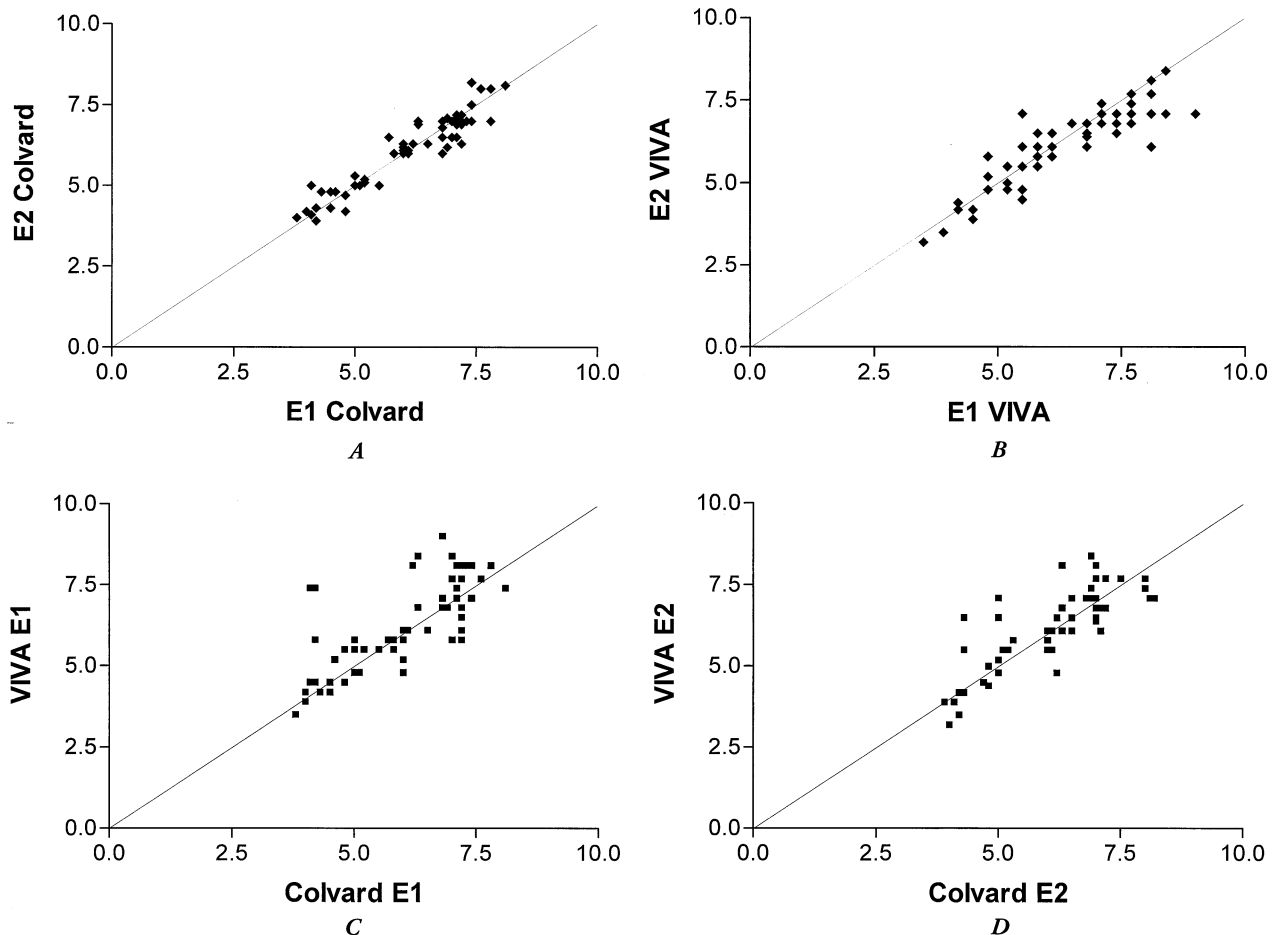


Figure 3. (Schnitzler) *A*: Pupil size (in millimeters) measured with the Colvard pupillometer (E1 versus E2). *B*: Pupil size (in millimeters) measured with the VIVA pupillometer (E1 versus E2). *C*: Pupil size (in millimeters) measured by E1 using the Colvard and VIVA pupillometers. *D*: Pupil size (in millimeters) measured by E2 using the Colvard and VIVA pupillometers.

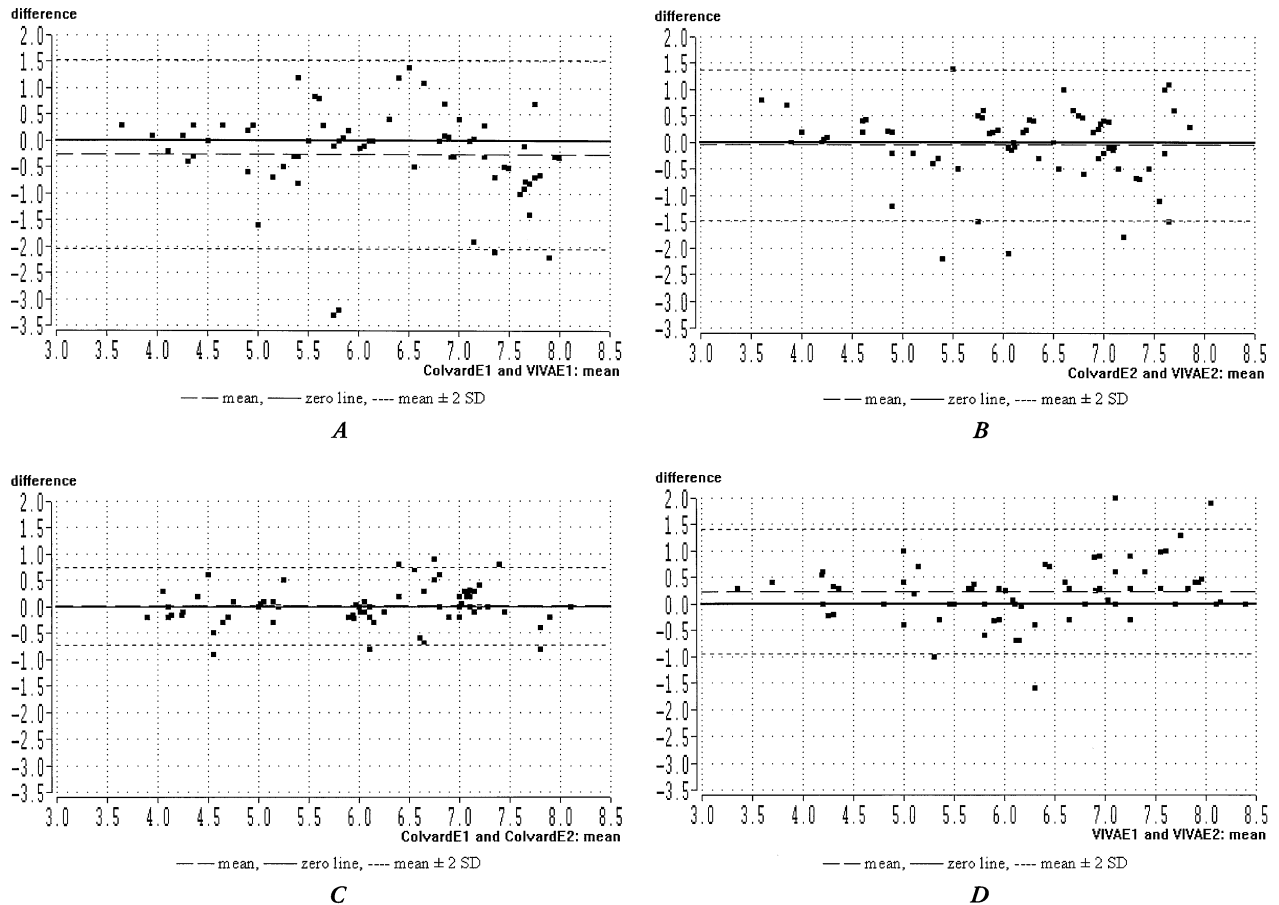


Figure 4. (Schnitzler) A: Agreement of the Colvard and the VIVA infrared pupillometers for measurements obtained by E1 (in millimeters). B: Agreement of the Colvard and the VIVA infrared pupillometers for measurements obtained by E2 (in millimeters). C: Interrater repeatability for the Colvard infrared pupillometer (in millimeters). D: Interrater repeatability for the VIVA infrared pupillometer (in millimeters).

Table 2. Limits of agreement between Colvard and VIVA measurements.

Comparison	Mean Difference $\pm$ SD (mm)	Limits of Agreement* (mm)	Range (mm)
Colvard–VIVA (E1)	-0.27 ± 0.89	-2.0, 1.5	3.5
Colvard–VIVA (E2)	-0.05 ± 0.7	-1.5, 1.4	2.9

E1 = examiner 1; E2 = examiner 2

*Mean difference $\pm$ 2 SD of the difference between Colvard and VIVA pupillometer measurements

Table 3. Limits of agreement between examiner 1 (E1) and examiner 2 (E2) measurements.

Comparison	Mean Difference $\pm$ SD (mm)	Limits of Agreement* (mm)	Range (mm)
E1–E2 (Colvard)	0.01 ± 0.37	-0.7, 0.7	1.4
E1–E2 (VIVA)	0.23 ± 0.59	-1.0, 1.4	2.4

*Mean difference $\pm$ 2 SD of the difference between Colvard and VIVA pupillometer measurements

Subjective Glare and Night Vision

No glare was reported by 5 participants, mild glare by 9, moderate glare by 12, and severe glare by 7. Very good night vision was reported by 8 participants, good night vision by 18, reduced night vision by 5, and very reduced night vision by 2. There was, however, no correlation between subjective glare sensitivity or reduced night vision and scotopic pupil diameter.

Scotopic Pupil Diameter, Measurement Variability, Age, and Eye Color

With the Colvard pupillometer, the correlation coefficient between scotopic pupil diameter and age by E1 was -0.53 in the right eye and -0.47 in the left eye and by E2, -0.45 and -0.41 , respectively. Using the VIVA pupillometer, the respective correlations for E1 were -0.53 and -0.50 and for E2, -0.51 and -0.48 (Figure 5). The mean correlation coefficient was $0.48 \pm$

Table 4. Scotopic pupil diameter measured with different devices.

Device	Number of Eyes	Age (years)	Scotopic Pupil Diameter	
			Mean $\pm$ SD	Range
Colvard—infrared	66	19–55	6.08 $\pm$ 1.16	3.2–8.4
VIVA—infrared	66	19–55	6.24 $\pm$ 1.28	3.5–9.0
Colvard—infrared ⁹	200	18–50	6.20	3.0–9.0
IOWA—infrared ¹⁰	14	28–42	4.95 $\pm$ 1.08	—
Rosenbaum—comparison ¹⁰	14	20–70	5.40 $\pm$ 1.10	—
Photographies (Nikon) ¹⁷	242	20–70	4.90 $\pm$ 0.80*	2.7–6.6

*Measured pupil size reduced 14% to account for corneal magnification

0.04 (range -0.41 to -0.53). Variability tended to decrease with increasing age.

Mean scotopic pupil diameter was 5.58 ± 1.24 mm in eyes with green irides, 6.24 ± 1.10 mm in eyes with brown irides, and 6.65 ± 1.17 mm in eyes with blue irides. The Student *t* test showed a statistically significant difference in pupil size between brown and blue eyes ($P = .018$), brown and green eyes ($P = .0001$), and green and blue eyes ($P = .0000008$).

Discussion

Current refractive procedures of the cornea and the implantation of phakic IOLs can lead to ocular aberrations such as increased glare, halos, or other bothersome symptoms.^{1–6} Reasons for these phenomena can be small ablation zones, optical distortion within the corneal ablation area, decentered ablation zones, and residual stromal scarring or a small or decentered phakic IOL

optic.^{12,13} Disturbance of vision and optical glare phenomena are produced when pupil diameter increases, especially at night. Daily and mainly night visual function, as well as quality of life, can be significantly affected.^{6,14} One possible way to prevent these complications is to precisely evaluate pupil diameter under scotopic illumination preoperatively and to consider the individual value when choosing the ablation zone or the phakic IOL.

Several studies have measured pupil diameter under scotopic light conditions (Table 4). Colvard⁷ found a mean pupil size of 6.2 mm (3.0 to 9.0 mm) using his device under the same room illumination described by Salz.⁶ Evaluation of pupil size with the IOWA infrared pupillometer (Henry Louis, Inc.) detected a mean pupil size of 4.95 ± 1.08 mm in participants aged 28 to 42 years. Ambient luminance for simulation of dim light conditions was 0.42 cd/m^2 .⁸ With the Rosenbaum card, measurement of the same patients revealed a mean pupil diameter of 5.4 ± 1.1 mm.⁸ The smaller pupil diameter might be the result of the different luminance condition.

Koch et al.¹⁵ studied testing conditions for pupils smaller than 5.0 mm using different levels of luminance and different fixating distances to permit the individualized estimation of the eye's bifocal function after implantation of an annular-design bifocal IOL. The 132 patients ranged in age from 20 to 70 years or older and were grouped according to age, with at least 20 in each group. Measurements were performed with a self-developed method for photographing pupils using a Nikon 8008 camera. Night driving was simulated by illumination of 0 ft-c and fixation on a distant target. Mean pupil diameter of all patients was 4.9 ± 0.8 mm. Considering corneal magnification of 14%,¹⁶ the authors reduced

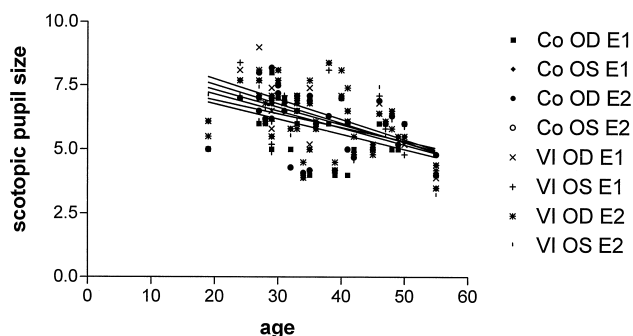


Figure 5. (Schnitzler) Correlation of scotopic pupil size and age; Colvard pupillometer (Co), VIVA pupillometer (VI), right eye (OD), left eye (OS), examiner 1 (E1), examiner 2 (E2). For example, Co OD E1 is the measurement of scotopic pupil size of the right eye by E1 using the Colvard pupillometer.

values of pupil measurement by this factor. When the value was recalculated, mean pupil diameter was about 5.6 mm. The smaller mean pupil diameter than that in our study is a result of the age range of the patients in the studies. In the age range between 20 and 50 years, considering corneal magnification, Koch et al. found a pupil size of about 6.0 mm, which is comparable to the mean pupil diameter in our study.

In our study, we showed that simple plotting of both methods of pupil measurement provides a good gauge of agreement for 2 examiners. By drawing plots as described by Bland and Altman,^{9,10} we found that although the mean difference between the Colvard and VIVA pupillometer was small, the limits of agreement were large. In Figure 4, most of the scatter points were within ± 2 SD, which indicates that the 2 methods are almost interchangeable. Compared with the results in the literature,^{7,8,15} our measurements with the VIVA pupillometer seem slightly overestimated, whereas measurements with the Colvard pupillometer delivered more similar data on scotopic pupil size. This indicates that measurements with the Colvard pupillometer are more precise.

There was a smaller mean difference in the results obtained by E1 than by E2, which indicates some variability. Comparison of mean differences by both examiners for the same device shows that data obtained with the Colvard pupillometer have a mean difference of almost 0, whereas there was a higher mean difference with the VIVA pupillometer. Limits of agreement were smaller with the Colvard than with the VIVA pupillometer. Therefore, measurements with the Colvard pupillometer are more reliable and precise. This is confirmed by the coefficients of interrater reliability, which were about a third smaller with the Colvard than with the VIVA pupillometer. This indicates better repeatability of Colvard than of VIVA pupillometer measurements.

Research of the relationship between pupil size, ablation zone, and visual quality has been performed. Davidorf⁶ postulates that to prevent all peripheral light rays from entering the pupil, the optical zone at the corneal plane should be larger than the pupil. O'Brart et al.¹ found that more patients have severe night vision disturbances when treated with a 5.0 mm ablation zone than computerized measurements of "night" halo in a 6.0 mm ablation group. A large scotopic pupil size is a possible explanation for this finding.

Verdon and coauthors¹⁷ found that low-contrast visual acuity increases after pupil dilation in patients who have had photorefractive keratectomy. It is not yet clear what the relationship between pupil size and ablation zone diameter should be to prevent disturbance of vision.

We support Colvard's opinion⁷ that the relationship between pupil size, optic quality, and patient satisfaction is multifactorial. We found in a 1999 retrospective analysis of our corneal refractive data that subjective postoperative glare occurs not only with large scotopic pupil diameters but also with small optical ablation diameters combined with large ablation depths.¹⁸ The relationship of optic size in phakic IOL implantation to pupil diameter may also influence postoperative glare.¹³

Until new studies are available, refractive surgeons should be aware of a mean pupil diameter of larger than 6.00 mm in a normal population. This should have an impact on the ablation zone (optical zone) of the cornea or the appropriate phakic IOL optic size in refractive surgery. Age and eye color of the patient affect scotopic pupil size. However, because of the high variance in pupil size, the individual value must be measured before refractive surgery. The Colvard pupillometer seems to be a useful and reliable device that is easy to handle. Further clinical studies should focus on the relationship between pupil size and postoperative outcome after photorefractive surgery of the cornea and after phakic IOL implantation.

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